

Sub. Form PTO-1449

INFORMATION DISCLOSURE
IN AN APPLICATION

(Use several sheets if necessary)

Sheet 1 OF 2

				Docket Number 107223.167 US2	Application Number 10/630,239
				Applicant Sanghvi, et al.	
				Filing Date July 30, 2003	Group Art Unit Not yet assigned 1615

U.S. Patent Documents						
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
as	5,128,143	7/7/92	Baichwal, et al.	424	464	
	5,135,757	8/4/92	Baichwal, et al.	424	465	
	5,455,046	8/29/95	Baichwal, et al.	424	454	9/8-7/7/06
	5,512,297	4/30/96	Baichwal	424	451	
	5,554,387	9/10/96	Baichwal	424	488	
	5,399,358	3/21/95	Baichwal, et al.	424	464	
	5,399,359	3/21/95	Baichwal	424	464	
	5,670,168	9/23/97	Baichwal, et al.	424	464	
	4,828,836	5/9/89	Elger, et al.	424	419	
	6,340,475	1/22/02	Shell, et al.	424	469	
	4,351,825	9/28/82	Sothmann, et al.	424	19	
	5,055,306	10/8/91	Barry, et al.	424	482	
	5,330,767	7/19/94	Yamamoto, et al.	424	497	
	5,611,971	3/18/97	Maedera, et al.	264	4.1	
	5,631,021	5/20/97	Okada, et al.	424	451	
	5,651,990	7/29/97	Takada, et al.	424	497	
as	3,629,393	12/21/97	Nakamoto, et al.	424	22	

Foreign Patent Documents						
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
as	99/47128	9/23/99	WO			
	97/17975	5/22/97	WO			
	44 32 757	3/21/96	DE			YES
	0 749 751	12/27/96	EP			
	0 580 428	10/1/97	EP			
	0 709 085	5/1/96	EP			
	0 531 497	8/13/97	EP			
as	0 251 459	7/8/92	EP			

Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)

EXAMINER <i>Alma J. Reit</i>	DATE CONSIDERED 07-07-06
EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609; Draw Line through citation if not conformance and not considered. Include copy with next communication to applicant.	

INFORMATION DISCLOSURE
IN AN APPLICATION

(Use several sheets if necessary)

Sheet

2

OF

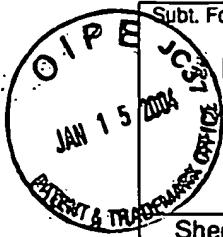
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Docket Number
107223.167 US2Application Number
10/630,239Applicant
Sanghvi, et al.Filing Date
July 30, 2003Group Art Unit
Not yet assigned

1615

q/s	A1	Campbell, et al., "A Clinical Evaluation of a Delayed Release Preparation of Metformin," <i>J Int Med Res</i> , Vol. 1, pp.551-556 (1973)
	A2	Pentikainen, "Bioavailability of Metformin. Comparison of solution, rapidly dissolving tablet, and three sustained release products," <i>Int J Clin Pharmacol, Ther and Toxicol</i> , Vol. 4, pp. 213-220 (1986)
	A3	Abdallah, et al., "Preparation and evaluation of metformin hydrochloride controlled-release tablets," <i>S.T.P. Pharma</i> , Vol. 4(1), pp. 15-20 (1988)
	A4	Karttunen, et al., "The Pharmacokinetics of metformin: a comparison of the properties of a rapid-release and sustained-release preparation," <i>Int J Clin Pharmacol, Ther and Toxicol</i> , Vol. 21(1), pp. 31-36 (1983)
	A5	Mosby's GenRx, "Drug Names – Metformin Hydrochloride (3204) Categories, Brand Names, Formularies & Cost of Therapy," (1998) pp.1-17
	A6	Saleh, 'Tablets produced under licence Do they have the same dissolution characteristics and drug content uniformity as the original ones? Example: metformin hydrochloride sustained-release tablets," <i>S.T.P. Pharma</i> , Vol. 6(8), pp. 598-603 (1990)
	A7	Grdinic, et al., "Comparison of in-vitro release and renal elimination of 1-butylbiguanide from times-release oral antidiabetic preparations," <i>Acta Pharm. Jugoslav.</i> , Vol. 29, pp. 215-221 (1979)
	A8	Dimitrijevic, et al., "Electro-Responsive Release From A Chondroitin Sulphate Hydrogel," <i>J. Pharm. Pharmacol.</i> , Vol. 47, pp. 1058 (1995)
	A9	Karttunen, "The Influence of Pharmaceutical Formulation on the Gastrointestinal Side Effects of Metformin," <i>Scandinavian Society for the Study of Diabetes</i> , 15 th Annual Meeting, Norway (1980)
	A10	Noel, "Kinetic Study of Normal and Sustained Release Dosage Forms of Metformin in Normal Subjects," <i>Research and Clinical Forums</i> , Vol. 1(4), pp. 35-50 (1979)
	A11	Noel, "Kinetic Study of Normal and Sustained Release Dosage Forms of Metformin in Normal Subjects," <i>Journal of International Biomedical Information and Data</i> , Vol. 1(1), pp. 9-20 (1980)
	A12	Bristol-Myers Squibb, "Glucophage XR (Metformin HC1 extended-release) Tablets, Rx," <i>FDA Website</i> , (Posted October 20, 2000)
	A13	"Glucophage Retard," The Rote Liste (1993)
	A14	Araman, et al., "In Vivo-In Vitro Correlation of Prolinged Release Metformin HCL Tablets Prepared with Coating Materials," <i>Supplement F, Supplement to Pharmaceutisch Weekblad Scientific Edition, 1st European Congress of Pharmaceutical Science</i> , Vol. 14(5) (1992)
q/s	A15	Stanforth, "Synergistically Interacting Heterodisperse Polysaccharides – Function in Achieving Controllable Drug Delivery," American Chemical Society (1993)

EXAMINER <i>Almendra M. Meza</i>	DATE CONSIDERED 07-07-06
EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609: Draw Line through citation if not conformance and not considered. Include copy with next communication to applicant.	



Sub. For, PTO-1449 INFORMATION DISCLOSURE IN AN APPLICATION <i>(Use several sheets if necessary)</i>				Docket Number 107223.167 (US2)	Application Number 10/630,239
				Applicant SANGHVI, et al.	
Sheet	1	OF	1	Filing Date July 30, 2003	Group Art Unit 1614 /615

U.S. Patent Documents

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
Q/S	5,955,106	9/21/99	Moeckel, et al.	424	464		

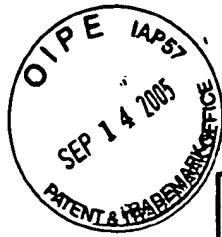
Foreign Patent Documents

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)

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EXAMINER <i>Quincey J. Reid</i>	DATE CONSIDERED <i>07-07-06</i>
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PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

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Substitute for form 1449A/B/PTO

Complete if Known

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/630,239-Conf. #9388
				Filing Date	July 30, 2003
				First Named Inventor	Pradeep P. SANGHVI
				Art Unit	1615
				Examiner Name	H. N. Sheikh
Sheet	1	of	1	Attorney Docket Number	0107223.00167US2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁴
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
Q/S	CA	DHOPESHWARKAR et al., Evaluation of Xanthan Gum in the Preparation of Sustained Release Matrix Tablets, Drug Development and Industrial Pharmacy, 19(9), 999-1017 (1993)	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	<i>Hinna N. Sheikh</i>	Date Considered	07-07-06
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